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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/858,207	05/15/2001	Helle Outrup	VAL6131P0208AUS	2878

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EXAMINER

MARX, IRENE

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 08/27/2002

3

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/858,207	Applicant(s) Outtrup et al.
	Examiner Irene Marx	Art Unit 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 18-23 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 18-23 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

- 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: _____ |

The application should be reviewed for errors.

The status of the parent case(s) should be updated.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 18, 21 and 22 are vague, indefinite and confusing in the recitation "pesticidally active fragment thereof", since the nature of this fragment is uncertain, even when reading the claims in light of the specification. Claims 21 and 22 compound the uncertainty further by claiming a fragment of a fragment.

Claim 19 is confusing and improper in having 2 periods at the end of the claim.

Claim 23 is vague, indefinite and confusing in that it is a product-by-process claim, wherein the product produced is a factor rather than the mutant claimed.

Claim 23 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 18-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for mutants obtained from strain *B. thuringiensis* subsp. *kurstaki* EMCC0086 having the required property, does not reasonably provide enablement for mutants derived from any strain of *B. thuringiensis* subsp. *kurstaki*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

From the record of the present written disclosure, the only strain of *B. thuringiensis* subsp. *kurstaki* shown to produce the factor a factor that potentiates the pesticidal activity of a

Bacillus thuringiensis δ-endotoxin by at least about 1.5 fold and mutated to obtain mutant strains that produce about two times more of the amount of the factor is the specific strain *B. thuringiensis* subsp. *kurstaki* EMCC0086. Moreover, the effect of the factor is specifically on *Bacillus thuringiinesis* pesticidal δ endotoxin. There is no clear definition on the record of "pesticidally active fragments" that have the required effects.

In addition, the screening protocol of the present disclosure is directed to generalized instructions to obtain mutants. Specification, page 8. The actual strains obtained are obtained by mutating one specifically known strain i.e., *B. thuringiensis* subsp. *kurstaki* EMCC0086. Table III shows the amount of factor Ia found by screening *Bacillus thuringiensis* products. However, this methodology does not provide guidelines to select suitable *B. thuringiensis* subsp. *kurstaki* parent strains that produce the required factor that potentiate the required activity. No specific guidelines are provided in the as-filed specification to enable one of ordinary skill in the art to screen and select for *B. thuringiensis* subsp. *kurstaki* to be mutated to produce mutants having the required properties. There is no indication as to a process of selection encompassing the recited species. It is well recognized in this art that the screening and selection for the production of a specific factor is unpredictable in this art in the absence of a specific screening protocol for the product to be produced from randomly selected strains.

The fact that applicants found one strain within the recited species to produce zwittermicin as a factor that potentiate the activity of δ-endotoxin or certain, specific, fragments thereof would not allow one of ordinary skill in the art to extrapolate to all mutants that produce certain factors in certain amounts and to all fragments that are pesticidal.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary to determine *B. thuringiensis* subsp. *kurstaki* strains suitable as parental strains; limited amount of guidance and limited number of working examples in the specification which pertain to mutants of a specific strain of *B. thuringiensis* subsp. *kurstaki* which produce more of the factor effective on specific *B. thuringiensis* pesticides; unpredictability in the art relating to "potentiation" and screening of suitable parental strains; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Thus, the scope of the claims is not commensurate with the teachings of enablement of the specification.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.

Irene Marx
Irene Marx
Primary Examiner
Art Unit 1651